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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) 966927.00006
LEDE.0006

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name: _____

Application Number	Filed
10/026,914	December 27, 2001

First Named Inventor
LINHART

Art Unit	Examiner
1645	HINES, Jana A.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

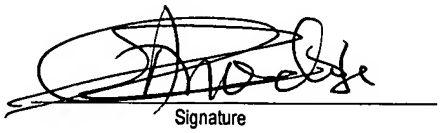
I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 48,293

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____



Signature

Chris E. Aniedobe
Typed or printed name

703-641-4200
Telephone number

August 15,, 2007
Date

Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Linhart, et al.	
	Art Unit: 1645
Appl. No. 10/026,914	Examiner: Jana A. Hines
Filed: December 27, 2001	Atty. Docket: 966927.00006 (0273-0006)
For: Allergy Vaccines Containing Hybrid Polypeptides	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attachment to Pre-Appeal Brief Request for Review

This Review is requested for the following errors and/or omissions of essential elements in the Office Actions dated June 20, 2007, February 0, 2007, June 15, 2007, and December 28, 2005.

In the Office Action dated June 20, 2007, February 01, 2007, the Examiner clearly and erroneously failed to recognize a distinction between a process of making and the product made. A process claim is patentable if it is unobvious and can be used to make another materially different product MPEP 806.05(f).

For instance, the Examiner rejected claims method claims 42-43, directed to a method of preparing fusion polypeptides consisting of timothy grass pollen allergens for use as immunotherapeutic agents, under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner's basis of rejection are that: Applicants failed to show that they have possession of the claimed genus of any polynucleotide sequence; that the genus of encoding polynucleotide sequences claimed is a large variable genus; that there was no disclosure of what the exact make-up of the fusion polypeptide is; that the Applicants failed to provide for the

structure of the polynucleotide or other identifying characteristics or properties other than the functionality of the polynucleotide encoding the fusion polypeptide; that when the claims recite "providing a polynucleotide encoding the fusion polypeptide", that "a" polynucleotide becomes an element of the invention to be construed to mean a single nucleotide as having the ability to encode the fusion polypeptide; that Applicants had not disclosed individual components or description of fragments thereof; and that the skilled artisan would be forced into undue experimentation to make and use the instantly claimed invention.

The above arguments by the Examiner are completely untenable where as here the relevant inquiry for the claimed method steps is whether the method steps have been adequately described. In prior filed Responses to the Office Action, Applicants enumerated support for each of the process steps in the specification, namely: (a) providing a polynucleotide sequence encoding the fusion polypeptide: See Figure 2. See also Example 2, page 11, paragraphs. (b) introducing said polynucleotide sequence into a host cell: See Example 3, Page 13 using E. coli as a host cell. (c) culturing the host cell obtained in b) under conditions such that the fusion polypeptide is expressed: See Example 3, page 13, paragraph 3. (d) recovering the expressed fusion polypeptide from the cultured host cell: See Example 3, page 13, paragraph 4. (e) testing the fusion polypeptide as candidate immunotherapeutic agents by administering said polypeptide to a test animal and selecting as immunotherapeutic agents those fusion polypeptides that induce IgE-blocking antibodies and induce stronger immune responses compared with the individual components or fragments thereof: See Example 5, page 15. See also Example 6, page 16.

Applicants believe that requiring the Applicants to disclose the primary structure of every timothy grass pollen allergen to which these method claims are applicable far exceeds the requirement of the law, where as here, the method claims can be, and are clearly understood by one of skill in the art, to be usefully applicable to materially different fusion polypeptides of timothy grass pollen allergens. The Examiner asserts, " that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species ..." Applicants' assignment of error is predicated on the fact that claims 42 and 43, the rejected claims, are directed to

a method and not a "claimed genus" and the entire assertions by the Examiner lack adequate basis in the law.

Further, claims 42-43 and 45 – 47 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to provide insufficient antecedent basis for "the individual components or fragments thereof." Applicants have pointed out to the Examiner that the individual components or fragments of those individual components are inherently recited in the phrase "fusion polypeptide" and the scope of the claims would be reasonably ascertainable by those skilled in the art. Inherent components of elements recited have antecedent basis in the recitation of the components themselves." MPEP § 2173.05(e). The MPEP provides an example: "the limitation 'the outer surface of said sphere' would not require an antecedent recitation that the sphere has an outer surface. Again, in a clearly erroneous application of the law, the Examiner asserts that "the doctrine of inherency refers (sic) the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103."

Further, claims 45-47 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ball et al. (WO 95/34578) in view of Vrtala et al. (1996. J. Allergy Clin. Immun., Vol. 97(3): 781 - 787). According to the Examiner, Ball et al. teach that the major grass pollen Phl p1 can be part of a hybrid or fusion polypeptide but does not specifically recite using another plant allergenic protein within the hybrid polypeptide. To cure the deficiency in Ball, the Examiner asserts that Vrtala et al., teach that DNA coding for three major timothy grass pollen allergens representing group I (Phl p1), group II (Phl p2) and group V(Phl p5) was known. Therefore, concludes the Examiner, "it would have been prima facie obvious at the time of applicants' invention to modify the plant polypeptide as taught by Ball et al., to include a different plant allergen as taught by Vrtala et al., to create a hybrid plant fusion allergen wherein said allergen is a fusion protein of two or more timothy grass pollen allergens."

Applicants believe that the Examiner's application of 35 U.S.C. 103(a) is clearly and manifestly erroneous. Not only has the Examiner not pointed to any credible

teaching, suggestion or motivation to make the alleged combination; the combination does not make enough commonsense to accord with the basic science under girding the present invention. Applicants are first to show that contrary to the then state of knowledge, that fusion proteins of known allergens can have therapeutic benefits. The Examiner on the other hand is asserting that whereas the individual allergens were previously known; and whereas there is also known a technique in biotechnology to boost the expression of recombinant protein by tagging sequences unto the target nucleotide in order to cause the micro-organism to express more of it than it normally would, that such teaching has already put into the public domain the fusion of timothy grass pollen allergens for immnunotherapy. Applicants believe that the Examiner's Application of the law in this instance is clearly and manifestly erroneous.

In view of the foregoing, Applicants respectfully request that a panel of Examiners review the above-mentioned issues in detail. Should there be any outstanding issues requiring discussion that would further the prosecution and allowance of the above-captioned application, the Office is invited to contact the Applicants' undersigned representative at the address and telephone number indicated below.

Respectfully submitted,

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Date: 08/15/2007

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